

§ 522.1884

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 59881, Oct. 20, 2003]

§ 522.1884 Prednisolone sodium succinate injection.

(a) *Chemical name.* 11 beta, 17, 21-Trihydroxypregna-1, 4-diene-3, 20-dione 21-succinate sodium salt.

(b) *Specifications.* Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10, 20, or 50 milligrams of prednisolone.

(c) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for products containing 10, 20, and 50 milligrams equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (d)(1), (2) (i), (ii), and (iii) of this section.

(d) *Conditions of use.* (1) The drug is intended for the treatment of horses, dogs, and cats.¹

(2)(i) The dosage for horses is 50 to 100 milligrams as an initial dose given intravenously over a period of one-half to 1 minute, or intramuscularly, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.¹

(ii) In dogs, the drug is administered intravenously at a range of 2.5 to 5 milligrams per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) In dogs and cats, the drug may be given intramuscularly for treatment of inflammatory, allergic and less severe stress conditions, where immediate effect is not required, at 1 to 5 milligrams ranging upward to 30 to 50 milligrams in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to 5 days if necessary. If permanent corticosteroid ef-

¹These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Ch. I (4–1–05 Edition)

fect is required oral therapy with prednisolone tablets may be substituted.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 13215, Feb. 20, 1981; 46 FR 33513, June 30, 1981; 52 FR 25212, July 6, 1987; 66 FR 23588, May 9, 2001]

§ 522.1885 Prednisolone tertiary butylacetate suspension.

(a) *Specifications.* Prednisolone tertiary butylacetate (Pregna-1,4-diene-3, 20-dione-11B, 17α 21-triol 21-(3,3, dimethyl butyrate) suspension contains 20 milligrams of prednisolone tertiary butylacetate per milliliter. It is sterile.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anti-inflammatory agent in horses, dogs, and cats.¹

(2) It is administered to horses intramuscularly at a dosage level of 100 to 300 milligrams and intrasynovially at a dosage level of 50 to 100 milligrams. It is administered intramuscularly to dogs and cats at a dosage level of 1 milligram per 5 pounds of body weight and intrasynovially at a dosage level of 10 to 20 milligrams. Intramuscular retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.¹

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 522.1890 Sterile prednisone suspension.

(a) [Reserved]

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 to 40 milligrams of prednisone.

Food and Drug Administration, HHS

§ 522.1940

(2) *Sponsor*. See 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer intramuscularly as follows:

(a) *Horses*. 100 to 400 milligrams, repeating if necessary. If no response is observed after 3 to 4 days of therapy, reevaluate diagnosis.¹

(b) *Dogs and cats*. 0.25 to 1.0 milligram per pound of body weight for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.¹

(ii) *Indications for use*. It is used for conditions requiring an anti-inflammatory agent.¹

(iii) *Limitations*.¹ Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushing's disease. With infections, use appropriate antibacterial therapy with and for at least 3 days after discontinuance of use and disappearance of all signs of infection. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 13446, Feb. 29, 1980, as amended at 50 FR 6160, Feb. 14, 1985; 52 FR 7832, Mar. 13, 1987]

§ 522.1920 Prochlorperazine, isopropamide for injection.

(a) *Specifications*. Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milligrams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to 0.28 milligrams of isopropamide) in buffered aqueous solution.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(2) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	Dosage in Milliliters
Up to 4	0.25
5 to 14	0.5-1
15 to 30	2-3
30 to 45	3-4
45 to 60	4-5
Over 60	6

Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 522.1940 Progesterone and estradiol benzoate.

(a) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000856 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), (c)(2)(iii), and (c)(3) of this section.

(2) No. 021641 for use as in paragraphs (c)(1) and (c)(2) of this section.

(b) *Related tolerances*. See §§ 556.240 and 556.540 of this chapter.

(c) *Conditions of use in cattle*. It is used for implantation as follows:

(1) *Suckling beef calves*—(i) *Amount*—(A) 100 milligrams (mg) progesterone and 10 mg estradiol benzoate (one implant consisting of 4 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 100 mg progesterone and 10 mg estradiol benzoate (one implant consisting of 5 pellets, each of 4 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use*. For increased rate of weight gain.